

REMARKS

Reconsideration and withdrawal of the objections to and the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 44-69 are now pending. Claims 44-69 have been added, and claims 30-43 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims, as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 USC 112. Changes to the claims, as presented herein, are not made for the purpose of patentability within the meaning of 35 USC sections 101, 102, 103 or 112. Rather, these changes are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the new claims is found throughout the specification and in the claims as originally presented.

Specifically, new claim 44 is based on original claim 30.

Support for claim 45 may be found on page 13, lines 1 and 2 of the specification.

Support for claim 46 may be found on page 10, line 2, and page 13, line 2, of the specification.

Claim 47 is based on claim 31.

Claim 48 is based on claim 32.

Claim 49 is based on claim 33.

Claim 50 is based on claim 39.

Claim 51 is based on claim 35.

Claim 52 is based on claim 36.

Support for claim 53 may be found on page 12, lines 2 and 3, and in original claim 36.

Claims 54, 55 and 56 are based on claim 36.

Claims 57 and 58 are based on claim 40.

Claim 59 is based on claim 37.

Claims 60-68 are based on claim 38.

Claim 69 is based on claim 41.

II. INFORMATION DISCLOSURE STATEMENT

Further to the Information Disclosure Statement filed December 28, 2000, the Examiner's attention is respectfully drawn to the documents listed on the accompanying PTO form 1449. In compliance with 37 C.F.R. §1.97(c), a check is enclosed which covers the required fee for entry of this Information Disclosure Statement.

III. THE SECTION 112 REJECTIONS ARE OVERCOME

Claims 30 and 32-43 were rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the use of lipases and/or esterases, allegedly does not reasonably provide enablement for the use of any random enzyme. The rejection is traversed.

Claims 30-43 have been cancelled, rendering the rejection moot.

However, the Office Action maintains that the specification does not provide sufficient guidance towards "the isolation, production, utilization, and functionality of any random various enzyme, of any source (save for instant claim 33) or class of enzyme." Applicants respectfully disagree.

The instant invention is clearly enabled because a skilled artisan would readily understand how to make and use the invention to, *inter alia*, isolate and produce enzymes which generate emulsifiers from fatty acid esters or which generate a second functional ingredient from a second constituent. According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988),

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted].

Id. at 1404.

Against this background, determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). For example, (1) the quantity of experimentation

necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

The skilled artisan would be in possession of the techniques for isolating enzymes, and would recognize that information regarding such techniques may be found in many standard textbooks. Additionally, the specification provides guidance as to the preferred sources for isolating such enzymes (*See* Specification, page 7, line 28 to page 8, line 3), and as to the type of enzyme preferred (*See* Specification, page 7, lines 1-5). Techniques relating to production of such enzymes, including recombinant DNA techniques, would also be readily known by one of skill in the art, and guidance pertaining to these techniques may also be readily found in standard textbooks.

Therefore, practicing the instant invention would not require undue experimentation as a skilled artisan would have the knowledge required to select an appropriate enzyme, with the guidance provided in the specification, which would act to generate an emulsifier. Consequently, reconsideration and withdrawal of the section 112, first paragraph rejection is respectfully requested.

Additionally, claims 30-43 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The rejection is respectfully traversed.

Claims 30-43 have been cancelled, rendering the rejection moot. However, as new claims 44-69 are based on original claims 30-43, some specifics of the Office Action will be addressed here.

A claim is definite if the scope of the subject matter embraced by a claim is clear and if the applicant has not otherwise indicated that he intends the claims to be of a different scope. *In re Borkowski*, 164 U.S.P.Q. 642 (C.C.P.A. 1970). The "distinctly claim" requirement of 35 USC § 112, second paragraph, means that the claims must have a clear and definite meaning when construed in light of the complete patent document. *Standard Oil Co. v. American Cyanamid Co.*, 227 U.S.P.Q. 293 (Fed. Cir. 1985). The test of definiteness is whether one skilled in the art would understand the scope of the claim when read in light of the specification. *Morton Int. Inc. v. Cardinal Chem. Co.*, 28 U.S.P.Q.2d 1190 (Fed. Cir. 1993). The degree of precision necessary is a function of the subject matter claimed. *Hybritech Inc. v.*

Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81, 94-95 (Fed. Cir. 1986). Indeed, the Federal Circuit noted in *Hybritech* that:

'[I]f the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more' [and] the claims are clearly definite.

Id. at 94 (citing to *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 U.S.P.Q. 634, 641 (Fed. Cir. 1985)) (emphasis added).

Applying the law to the instant facts, as the instant claims, read in light of the specification, apprise a skilled artisan of both the utilization and scope of the invention, and as the language is as precise as the subject matter permits, the instant claims are definite. A contrary conclusion, as posited by the Office Action, would not only be against public policy, but also impermissible as a matter of law. *Hybritech*, 231 U.S.P.Q. at 95 ("As a matter of law, no court can demand more.").

Specifically, the Office Action rejected the use of "generated" as indefinite in claims 30, 34, and 39, stating that "it is unclear if this implies (a) the triglyceride is broken down to produce small compounds, including an emulsifier, (b) the action of the enzyme couples the triglyceride with an additional (unspecified) compound, to form an emulsifier, or (c) a combination of both." Office Action at 3. The term "generated" is a broad term, which encompasses a number of different ways in which the emulsifier and/or second functional ingredient may be produced by enzymatic action. The term includes the situations presented in the Office Action, and is intended to include them. As one skilled in the art would recognize, the present invention provides for a number of enzymes to be utilized in the practice of the invention. It would be remiss to utilize a more narrow term than "generated" and in the process exclude the methods of action of any of the enzymes available for the practice of the invention. Therefore, it is respectfully submitted that while the term "generated" is broad, it is not indefinite.

Additionally, the Office Action states that the use of both "esterase" and "lipase" in claim 31 is indefinite as "esterase" is a broad range within which "lipase" may be classified. Applicants disagree.

While the terms "lipase" and "esterase" may overlap, as some lipases have esterase activity, not all lipases have such esterase activity, thereby preventing "lipase" from being considered part of the range "esterase."

In claims 31, 36 and 37, the term "derivative" was considered indefinite by the Office Action. Again, Applicants disagree. One skilled in the art would be aware that "derivative" commonly refers to and encompasses simple chemical variations, which may or may not alter the function of the enzyme, functional derivatives and recombinant enzymes with natural or non-natural mutations. Consequently, the term "derivative" is definite.

Claim 38 was considered indefinite as "it is unclear how the simple reaction method of claim 30, from which it depends, is to 'provide the foodstuff' as recited in claim 38." Office Action at 5. Applicants respectfully disagree. Original claim 30 claims "A process for preparing a foodstuff suitable for consumption comprising an emulsifier, the process comprising the steps of..." The use of the term 'comprising' means that the process may therefore comprise additional steps. Claim 30 recites only the steps which are essential features of the present invention, to which additional steps may be added to provide the foodstuff of claim 38.

Additionally, the Office Action maintains that the use of the term "spreads" is indefinite. Submitted herewith as a copy of "Council Regulation (EC) No. 2991/94 of 5 December 1994 laying down standards for spreadable fats" (Official Journal of the European Communities, No. L 316/2), which sets regulations for spreads (See Article 1, section 2) as set forth in the Annex. It is respectfully pointed out that the term "spread" is used to describe all of the products described in the Annex, regardless of which of the three categories (A, B, or C) they are assigned to. In contrast, "margarine" is specifically defined in fat group B, and is absent from fat groups A and C. As before, "margarine" cannot be considered a component of the term "spreads" as "spreads" refers to three distinct classes of items, two of which "margarine" is excluded from. Therefore, it is clear that "margarine" is distinguishable from the term "spreads" and not a subset of "spreads."

The term "foodstuff" was allegedly unclear in claim 39. The Office Action states that the addition of the term "resultant" would make the claim more clear in meaning. Applicants disagree. In claim 39, it is clear that the foodstuff is provided by step (iii) of the claimed process. Therefore, prior to the claimed process steps, there is not foodstuff present as defined in the present application. Rather, "food material" (i.e. ingredients) is present. Therefore, as there is an obvious difference between "food material" and "foodstuff", the term "resultant" is not deemed necessary.

Claim 39 is also allegedly unclear in the use of the term "second functional ingredient." Applicants disagree. It is respectfully pointed out that at page 3, line 28 to page 4, line 2, of the

present application, the term "functional ingredient" is defined as a constituent of the foodstuff which performs a specific function in the foodstuff, preferably an emulsifier, hydrocolloid, preservative, antioxidant, coloring, flavoring and/or viscosity modifier.

It is respectfully submitted that the remainder of the specific instances of indefiniteness provided by the Office Action have been addressed in the Amendment to the claims.

Consequently, reconsideration and withdrawal of the section 112 rejections is respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 30 to 43 were rejected under 35 U.S.C. §102(e) as being allegedly anticipated by Schneider et al. (WO 92/14830).

Claims 30-32, 34-36, 38-39 and 41-43 were rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Van Den Ouweland et al. (U.S. Patent No. 5,695,802).

Claims 30-43 were rejected under 35 U.S.C. §102(e) as being allegedly anticipated by Michelsen et al. (U.S. Patent No. 6,143,543).

Claims 30-36, 38-39 and 41-43 were rejected under 35 U.S.C. §102(b) as being allegedly anticipated by either of Moore et al. (EP 0 652 289) or McNeill et al. (EP 0 445 692).

The rejections are traversed, and will be addressed collectively.

Claims 30 to 43 have been cancelled, rendering the rejections moot. However, as the new claims are based on claims 30 to 43, we now set forth arguments as to why the currently pending claims are not anticipated by the aforementioned references.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. See *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. See *Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. See *In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, the documents relied upon by the Office Action do not disclose, suggest or enable Applicants' invention.

More specifically, Schneider et al. involves a method for the production and specific precipitation of pure 1-monoglycerides which comprises the steps of mixing glycerol with an enzyme and an acyl donor in a selected solvent. Suitable solvent systems are described at page 24, lines 22 to 29 of the reference, and consist of either t-BuOMe and n-hexane or 100% n-hexane. It is further taught on page 21, lines 29-33 that "after complete or desired conversions of the substrates to products have been achieved, the solid support and the enzyme are removed by conventional means such as simple filtration or centrifugation." This is repeated in Example 1, wherein it is stated that "the enzyme was removed by filtration" (page 28). This passage was also pointed out in the Office Action at page 6.

The present invention is directed to a process for preparing a foodstuff. The term "foodstuff" is defined at page 4, line 4 of the instant application as "a substance suitable for human or animal consumption." Step (ii) of the present invention (see, for example, claim 44), recites "inactivating or denaturing the enzyme to provide the foodstuff comprising ... the enzyme in an inactive form or a denatured form." Step (ii) of the instant invention is in sharp contrast to Schneider et al., in which the enzyme is removed. Schneider et al. does not describe inactivating or denaturing the enzyme such that it is present in the foodstuff in either an inactive form or a denatured form. In Schneider et al., the filtration process ensures that the enzyme is not present. As the presence of the enzyme in a denatured or inactivated form is a limitation of the present claims, one which clearly is not recited in Schneider et al., the present invention is not anticipated by Schneider et al.

Additionally, the system in Schneider et al. is not a foodstuff as defined in the instant application. The product of Schneider et al. contains an organic solvent such as hexane or t-BuOMe, the presence of which would render the product unfit for human or animal consumption, which would exclude the product of Schneider et al. from the instant definition of foodstuff. Again, as Schneider et al. does not contain every aspect of the instant claims, it is respectfully submitted that the rejection cannot stand.

Similarly, Van Den Ouweland et al. does not disclose or suggest all the elements of the instant claims. Specifically, claim 44 relates to a process for preparing a food stuff comprising an emulsifier, the process comprising (i) contacting a food material containing a fatty acid ester and a second constituent with an enzyme such that an emulsifier is generated by the enzyme from the fatty acid ester and a second functional ingredient is generated from the second

constituent, and (ii) inactivating or denaturing the enzyme to provide the foodstuff comprising the emulsifier, the fatty acid ester and the enzyme in an inactive or denatured form.

Van Den Ouweland does not disclose or suggest the presence of a second constituent in the food material, nor the generation of a second functional ingredient from a second constituent. Consequently, as Van Den Ouweland et al. does not contain all the elements of the instant claims, the rejection cannot stand.

Additionally, Applicants respectfully point out that Michelsen et al. is not available as a reference under Section §102(e) as Michelsen et al. and the present application share a common assignee, Danisco A/S; See 35 U.S.C. § 103(c), and note the filing date of the instant application.

However, it is submitted that the present invention is novel and nonobvious over Michelsen et al. While Michelsen et al. may mention "glyceride oligomers", this is not a term that is meaningful to one skilled in the art in the context of Michelsen. Specifically, it is respectfully submitted that the skilled artisan would recognize that this term had arisen from a typographical error, and would have assumed that the correct term was "glucoside oligomers," since Michelsen et al relates to sugar oligomers.

Consequently, Michelsen et al. does not teach or suggest that glyceride monomers would be suitable substrates for the enzyme system comprising a ferulic acid esterase from *Aspergillus niger* that is useful for preparing food and feed, in particular dough and bakery products with an enzyme substrate that is preferable wheat, beet or corn. Additionally, Michelsen et al. does not teach or suggest that the enzyme may generate an emulsifier, and in particular, Michelsen does not teach or suggest that the enzyme may generate an emulsifier form a fatty acid ester.

The Office Action also states that wheat and corn naturally contain triglycerides and sugars, such that addition of the esterase to these food materials constitutes following the method steps of the present invention, and such addition would be expected to yield an emulsifier and a "by-product secondary compound." Office Action also states that in Example G of Michelsen et al., upon completion of the reaction, the enzyme is freeze-dried and thereby inactivated.

Applicants maintain that Michelsen et al. does not clearly and unambiguously teach or suggest to the reader the use of a food material comprising fatty acid esters such as triglycerides in order to produce an emulsifier *in situ*. Instead, Michelsen et al. teaches the break-down of plant cell walls to provide improved dough handling properties. Furthermore, the freeze-drying of the enzyme does not equate to inactivation of the enzyme as in the present invention, as the effects of freeze-drying the enzyme are temporary.

Consequently, for all of the reasons set forth above, Michelsen et al. does not anticipate or render obvious the present invention.

The Office Action stated that Moore et al. discloses the hydrolysis of triglycerides in the presence of diglycerides and water, to yield randomly interesterified triglycerides, as well as diglycerides, and monoglycerides by using the lipase from *Mucor miehei*. The Office Action continues by stating that hydrochloric acid is used to stop the action of the enzyme (col. 6, lines 20-21) and that since the method steps are the same as those of the present invention, it would be expected that the same enzymatic reactions would yield "an emulsifier" compound as well as a by-product secondary compound(s).

Contrary to the assertions of the Office Action, it is respectfully submitted that the only portion of Moore et al. which involves any type of denaturing of the enzyme is at column 6. However, this passage is part of a section starting at column 5, line 45 and headed "lipolysis". This section, as explained at column 8, line 55 to column 9, line 3, merely describes an analytical technique used to analyze the randomly inter-esterified triglycerides produced by the process of Moore et al., and is not itself part of that process. However, as taught in the lipolysis section, at column 5, lines 47 to 51 of Moore et al., "the fat or oil to be analyzed is ...passed through an alumina column ...to remove...partial glycerides" before being subjected to the analytical technique. Thus, the resultant sample for analysis contains only triglycerides and does not contain a second constituent, as called for by the present claims. Therefore, the only occasion when the enzyme is "denatured" is when no second constituent is present. As this is contrary to the present invention, wherein the denatured enzyme is present along with a second constituent, Moore et al. does not teach or suggest all of the elements of the claims, making the rejection improper.

Additionally, at all other instances in Moore et al., the lipase is supported on Duolite. Clearly, if the enzyme is on a support, there is no need to inactivate or denature the enzyme, such that the resultant "foodstuff", if any, would not comprise an inactivated or denatured enzyme, again, showing that Moore et al., does not contain all elements of the instant claims.

Accordingly, Moore fails to teach or suggest the instant invention.

Finally, McNeill et al. is described as relating to the production of monoglycerides as emulsifying agents, however, it does not teach or suggest the production of a foodstuff. The present invention relates to a process for preparing, *inter alia*, an emulsifier *in situ* in a foodstuff, and not to an industrial method of producing monoglycerides. Furthermore, McNeill et al., does

not disclose or teach or suggest the inactivation or denaturing of the enzyme, nor the presence of the enzyme in the monoglyceride product, thereby showing that McNeill et al. does not teach or disclose or suggest all elements of the present claims, rendering the rejection inappropriate. X

Consequently, reconsideration and withdrawal of the section 102 rejections is respectfully requested.

REQUEST FOR INTERVIEW

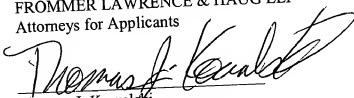
If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested. The Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.)

CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants


Thomas J. Kowalski
Reg. No. 32,147
(212) 588-0800